EXHIBIT C

United States Department of Justice

THE UNITED STATES ATTORNEY'S OFFICE
SOUTHERN DISTRICT of NEW YORK

U.S. Attorneys » Southern District of New York » News » Press Releases

Department of Justice

U.S. Attorney's Office

Southern District of New York

FOR IMMEDIATE RELEASE Wednesday, December 16, 2015

Manhattan U.S. Attorney Announces $39 Million Civil Fraud Settlement Against Qualitest Pharmaceuticals For Selling Half-Strength Fluoride Supplements

Preet Bharara, the United States Attorney for the Southern District of New York, Scott J. Lampert, Special Agent in Charge of the New York Regional Office for the Office of Inspector General for the Department of Health and Human Services ("HHS-OIG"), and Diego Rodriguez, the Assistant Director-in-Charge of the New York Office of the Federal Bureau of Investigation ("FBI"), and Patrick E. McFarland, the Inspector General for the U.S. Office of Personnel Management ("OPM") announced a $39 million settlement against Vintage Pharmaceuticals, LLC, *d/b/a* QUALITEST PHARMACEUTICALS; Vintage'S corporate parent Endo Pharmaceuticals, Inc.; and seven of their corporate subsidiaries or affiliates (collectively, "QUALITEST") in a civil fraud lawsuit. This global settlement resolves federal claims under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, that allege QUALITEST sold chewable fluoride tablets that contained less than half the amount of fluoride ion indicated on the drug label and caused federal healthcare programs to be fraudulently billed for these tablets, and also will resolve numerous state law civil fraud claims.

The Government simultaneously intervened in and settled this lawsuit, which was initially filed by a whistleblower. As alleged in the Government's intervention papers, QUALITEST violated the False Claims Act by knowingly manufacturing and selling understrength chewable fluoride tablets that were prescribed to children living in communities without fluoridated water supply to prevent tooth decay, and causing Medicaid and the Federal Employees Health Benefits Program to pay millions of dollars for these understrength tablets. Today, U.S. District Judge Denise Cote approved a settlement stipulation to resolve the Government's claims against QUALITEST. Under that settlement, QUALITEST agrees to pay $22.44 million to the Government to resolve the federal civil fraud claims and make extensive admissions. Further, as part of the global settlement, QUALITEST will pay approximately $16.56 million to the settling states to resolve state law civil fraud claims.

Manhattan U.S. Attorney Preet Bharara said: "The integrity of federal healthcare programs like Medicaid depends on manufacturers telling the truth about their drugs and producing and labelling their drugs accurately. When companies violate that critical obligation, as Qualitest did here by distributing diluted fluoride and then causing health care programs to pay for the full strength tablets, we will pursue them, make them pay damages and admit to their violations."

HHS-OIG Special Agent in Charge Scott J. Lampert said: "It is shocking that a pharmaceutical company would knowingly distribute diluted fluoride meant to provide preventative dental benefits to children as if it were full strength. We remain committed to investigating companies that put greed over their professional obligations to serve their customers and honestly bill for their products."

FBI Assistant Director-in-Charge Diego Rodriguez said: "Qualitest knowingly exploited federal healthcare programs and misrepresented the quality of fluoride tablets provided to children in need of these supplements. Today's settlement brings us one step closer to tackling the misuse of public funds."

OPM Inspector General Patrick E. McFarland said: "Qualitest's actions are unconscionable and put the health and wellbeing of children at risk. I am proud that we were able to work with our law enforcement partners to hold Qualitest accountable for its offenses. We remain committed to ensuring that the health of Federal employees and their families are protected and that such unscrupulous behavior is caught and punished."

As part of the settlement, QUALITEST admitted that they manufactured and sold chewable fluoride tablets from 2007 to July 2013 and that they knew federal healthcare programs, including Medicaid, were a significant source of coverage of QUALITEST's fluoride tablets. QUALITEST also admitted that, since at least 1994, guidelines issued by the American Dental Association and the American Academy of Pediatrics recommended that, to prevent tooth decay, fluoride supplements be prescribed to children living in communities without fluoridated water supply in doses of 1.0 mg, 0.5 mg, or 0.25 mg of fluoride ion per day, depending on a child's age and the local water fluoridation level. Further, QUALITEST admitted that the drug labeling for their chewable fluoride tablets stated that those tablets contained 1.0 mg, 0.5 mg, and 0.25 mg of fluoride and the drug labeling specifically referenced the guidelines from the American Dental Association and the American Academy of Pediatrics.

However, as QUALITEST's admissions show, QUALITEST's manufacturing processes were not designed to produce chewable fluoride tablets that would contain 1.0 mg, 0.5 mg, and 0.25 mg of fluoride ion per tablet. Specifically, as QUALITEST admitted, instead of using the amount of sodium fluoride that would result in the tablets containing the correct amount of fluoride ion, QUALITEST used less than half the appropriate amount of sodium fluoride. As QUALITEST further admitted, this caused children taking the QUALITEST fluoride tablets to receive less than half the amount of fluoride ion recommended by the American Dental Association and American Academy of Pediatrics guidelines.

The allegations of fraud stated in the Complaint were first brought to the attention of the Government by Dr. Stephan Porter, who filed a lawsuit in early 2013 under the *qui tam* provisions of the False Claims Act. In August 2013, and after the Government began its investigation into the whistleblower's allegations, QUALITEST stopped making and selling their chewable fluoride tablets. Under the settlement approved earlier today, the Government agreed to pay Dr. Porter approximately $4.71 million pursuant to the False Claims Act's *qui tam* provisions.

* * *

The False Claims Act permits the Government to recover up to three times the amount of damages incurred by the United States, in addition to civil penalties ranging from $5,500 to $11,000 per violation. Private parties who have knowledge of fraud committed against the Government may file suit on behalf of the Government and share in any recovery. The United States may then intervene and file its own lawsuit for treble damages and penalties, as it did in this case.

Mr. Bharara praised the extensive investigative work undertaken by HHS-OIG, the FBI, OPM-OIG, and the Food and Drug Administration's Office of Criminal Investigations, as well as close collaboration by the Medicaid Fraud Control Units for New York and Oregon.

The case is being handled by the Office's Civil Frauds Unit. Mr. Bharara established the Civil Frauds Unit in March 2010 to bring renewed focus and additional resources to combating healthcare and other types of frauds. Assistant U.S. Attorneys Li Yu and Jean-David Barnea are in charge of the case.

Attachment(s):
Download qualitest_federal_stipulation_so-ordered.pdf

Component(s):
USAO - New York, Southern

Press Release Number:
15-326

Updated December 17, 2015